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10/810,449	03/26/2004	Paul J. DeGroot	P-9891.05	8960

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EXAMINER	
PATEL, NATASHA	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,449	DEGROOT ET AL.	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☒ Claim(s) *2,3,8,9,15,20,21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8 October 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 17-27 of U.S. Patent No. 6,718,204. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons given below.

2. Regarding Claims 1-4, Claim 1 of the patent is equivalent, for the most part, in scope to the present invention.

3. Regarding Claim 5-17, Claims 2-14, respectively, of the patent are equivalent in scope to the present invention.

4. Regarding Claims 18, 20, and 21, Claim 17 of the patent is equivalent, for the most part, in scope to the present invention.

5. Regarding Claim 19, Claim 18 of the patent is equivalent, for the most part, in scope to the present invention.

6. Regarding Claims 22-30, Claims 19-27, respectively, of the patent are equivalent in scope to the present invention.

Claim Objections

7. Claims 2, 3, 20 and 21 are objected to because of the following informalities: BCC and DCC are undefined in the claims. Acronyms should be spelled out at least for the first instance they are introduced. Appropriate correction is required.

8. Claims 8 and 9 are objected to because of the following informalities: It is unclear as to what the second parameter refers to in Claim 8 until one reads Claim 9. It is suggested that these two claims be switched to prevent any misunderstandings. Appropriate correction is required.

9. Claim 15 is objected to because of the following informalities: VT is undefined in the claims. Acronyms should be spelled out at least for the first instance they are introduced. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Drane et al. (US Patent 5,215,083).

Regarding Claims 1 and 18, Drane discloses a system for use in controlling electrical therapy delivered to a heart (see col. 3, lines 44-68), comprising: a first circuit (see charge voltage level 30, charge control 31, shock control 32, and dump control 34) that is charged to deliver high-voltage electrical stimulation to the heart; a second circuit (see pacing circuit 35) to deliver anti-tachy pacing (ATP) therapy to the heart; a control circuit (see microprocessor 16) coupled to the first and second circuits (see Figure 1) to adjust a time of charging of the first circuit relative to a time of delivering ATP therapy based on predetermined criteria (see col. 4, lines 1-11).

12. Claims 1, 2, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Olson (US Patent 5,458,619).

13. Regarding Claims 1 and 18, Olson discloses a system for use in controlling electrical therapy delivered to a heart (see col. 2, lines 54-60), comprising: a first circuit that is charged (see high voltage charging circuitry 52) to deliver high-voltage electrical stimulation to the heart; a second circuit (see pacer circuitry 10) to deliver anti-tachy pacing (ATP) therapy to the heart; a control circuit (see control circuitry 4) coupled to the first and second circuits (see Figure 1) to adjust a time of charging of the first circuit relative to a time of delivering ATP therapy based on predetermined criteria (see col. 1, line 63-col. 2, line 5).

14. Regarding Claim 2, Olson discloses the control circuit includes means for operating in an ATP-DCC mode to initiate charging of the first circuit during delivery of the ATP therapy (see col. 1, lines 61-62).

15. Claims 1-4, 12-13, 18-22, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey, III et al. (US Patent 5,318,591).

16. Regarding Claims 1 and 18, Causey discloses a system for use in controlling electrical therapy delivered to a heart (see col. 3, lines 21-41), comprising: a first circuit (see rapid charge circuit 54) that is charged to deliver high-voltage electrical stimulation to the heart; a second circuit (see anti-tach pacing circuit 23) to deliver anti-tachy pacing (ATP) therapy to the heart; a control circuit (see control logic and timing circuits 22) coupled to the first and second circuits (see Figure 1) to adjust a time of charging of the first circuit relative to a time of delivering ATP therapy based on predetermined criteria. The examiner considers that the first circuit is charged to deliver high voltage electrical stimulation when that level of therapy is needed (see col. 8, lines 51-55).

17. Regarding Claims 2 and 20, Causey discloses the control circuit includes means for operating in an ATP-DCC mode to initiate charging of the first circuit during delivery of the ATP therapy (see col. 3, lines 60-61).

18. Regarding Claims 3 and 21, Causey discloses the control circuit includes means for operating in an ATP-BCC mode to initiate charging of the first circuit after the delivery of the ATP therapy (see col. 3, lines 61-64).

19. Regarding Claims 4 and 22, Causey discloses the control circuit includes means for transitioning between the ATP-BCC mode and the ATP-DCC mode based on

predetermined criteria related to the effectiveness of the previously-delivered ATP therapy (see Figure 3). The examiner considers that the control circuit is in ATP-DCC mode between t6 and t7 (ATP and charging occurs), and transitions to BCC mode from t7 to t8 (charging occurs after ATP has been delivered). The examiner further considers that the verification step, performed by the sensing circuit and the control circuit (see col. 10, lines 3-7), is the means for transitioning. Furthermore, the effectiveness of the ATP therapy is monitored by determining how successful or unsuccessful the therapy is at terminating the abnormal rhythm (see col. 12, lines 3-16). The amount of time spent delivering ATP therapy is based on the predetermined set of criteria, or programmed number of times that the therapy is allowed to fail before the next tier of therapy is applied.

20. Regarding Claims 12 and 19, Causey discloses a storage device (see memory 44) coupled to the control circuit (see Figure 1) to store the predetermined criteria (see col. 13, lines 25-35), and wherein the predetermined criteria is programmably selected (see col. 14, lines 5-8) to be specific to a given patient (see col. 15, lines 19-24).

21. Regarding Claim 13, Causey discloses at least one electrode coupled to the control circuit capable of detecting rhythms of the heart (see col. 7, lines 30-42), and wherein the predetermined criteria is based on a length of one or more of the detected rhythms of the heart. Since the control circuit 22 measures heart rate (see col. 7, lines 35-42) and information concerning the length of a cardiac rhythm is included in the heart rate, then control unit 22 takes the length of the cardiac rhythm into consideration when programming the predetermined criteria (see col. 7, lines 57-59).

22. Regarding Claim 30, Causey discloses further including discontinuing step a.) after unsuccessfully delivering ATP therapy a predetermined number of times (see col. 12, lines 6-9 and Figure 3). For example, after three unsuccessful deliveries of ATP therapy, ATP therapy is discontinued (at t7).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

24. Claims 5-11, 23-26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. (US Patent 5,318,591) in view of Sun et al. (US Patent 6,400,986).

25. Regarding Claims 5 and 24, Causey does not disclose a transition from ATP-BCC mode to ATP-DCC mode based on ATP therapy failure. Sun discloses a similar control system in which the transitioning modes based on the number of failed ATP therapy attempts to provide a means to effectively alter the therapy so the arrhythmia is rapidly and effectively treated so as to not require a defibrillation shock (see col. 2, lines 13-17 and col. 7, lines 33-35). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to charge Causey's capacitors during ATP to avoid unnecessary defibrillation therapy (see col. 2, lines 13-17).

26. Regarding Claim 6, Causey discloses the first parameter is measured as a number of failed ATP attempts out of a total number of ATP therapy attempts delivered (see col. 14, lines 2-14). The examiner considers that even if the ATT pacing is not repeated and the ICD steps up to the next tier, the number of failed attempts (1 failure) out of a total number of attempts (1 attempt) is still programmed into the control unit.

27. Regarding Claims 7 and 25, Causey does not disclose a transition from ATP-DCC mode to ATP-BCC mode in the case that ATP therapy is successful. Sun discloses transitioning modes based on the number of successful ATP therapy attempts in the ATP-DCC mode to provide a means to effectively alter the therapy so the arrhythmia is rapidly and effectively treated so as to not require a defibrillation shock (see col. 2, lines 13-17 and col. 7, lines 35-38).

28. Regarding Claim 8, Causey discloses a programmable (see col. 8, lines 26-27) storage device (see memory 44) coupled to the control circuit (see Figure 1) to store the predetermined criteria (see col. 14, lines 5-8).

29. Regarding Claim 9, Causey discloses the second parameter is measured as a number of successful ATP attempts out of a total number of ATP therapy attempts delivered (see col. 13, line 66-col. 14, line 2). The examiner considers that when the ATT pacing is successful, the ICD is inherently checking for a ratio of successful attempts (1 success) to a total number of attempts (1 attempt), which is programmed into the control unit.

30. Regarding Claim 10, Causey discloses at least one electrode (electrode 32) coupled to the control circuit (see Figure 1) to sense cardiac rhythms (see col. 7, lines

31-34), and a processing circuit (logic circuits) coupled to the control circuit to analyze types of the cardiac rhythms (see col. 8, lines 12-15), and wherein the predetermined criteria takes into account the types of the cardiac rhythms (see col. 8, lines 15-26) occurring in the heart. The examiner considers that the different types of cardiac rhythms include: normal, tachycardia, and fibrillation.

31. Regarding Claim 11, Causey discloses that the control circuit includes means for utilizing different values for the first and second parameters, each of the values being respectively associated with a type of cardiac rhythm occurring during delivery of the ATP therapy (see col. 12, lines 3-16 and col. 13, lines 25-35). The examiner considers that in the specific example give in column 12, the first parameter is set to three for first tier therapy, one for second tier therapy, and one for third tier therapy, where each tier represents a type of cardiac rhythm. Thus, it is evident that different values are assigned for each tier.

32. Regarding Claim 23, see rejections of similarly worded Claims 5 and 7 above.

33. Regarding Claims 26 and 29, Causey discloses analyzing the rate and regularity of cardiac rhythms in the heart (see col. 7, line 40-42). Causey does not disclose analyzing the morphology, however. Sun discloses analyzing morphology of cardiac rhythms detected in the heart and wherein the predetermined set of criteria in step c.) is based on the morphology of cardiac rhythms detected in the heart (see col. 5, lines 49-56). Sun further discloses changing modes based on change in morphology of the rhythm (see col. 3, lines 49-51). It would be obvious to one of ordinary skill in the art at the time of the invention to analyze the morphology of cardiac rhythms because Sun

teaches that it helps to differentiate between VT's and fibrillations (see col. 5, lines 56-60) thereby allowing Causey's control system to provide an appropriate therapy.

34. Claims 14-17 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. (US Patent 5,318,591) in view of Sun et al. (US Patent 6,400,986) as applied to Claims 5-10 above, and further in view of Haluska et al. (US Patent 4,830,006).

35. Regarding Claims 14-15 and 27-28, Causey discloses means for adjusting the time of charging of the first circuit relative to the time of delivering ATP therapy (see col. 11, lines 34-56). Causey does not disclose that this adjustment is based on the frequency of occurrence of one or more of the cardiac rhythms. Haluska discloses adjusting therapy based on a frequency of occurrence of the rhythm to provide rapid and effective treatment (see col. 7, lines 38-44 and col. 13, line 29-col. 14, line 36). The examiner considers that the detection of VT storms, wherein a predetermined number of VT rhythms are detected within a predetermined period of time, is equivalent to the frequency of occurrence of a VT, a specific cardiac rhythm. It would have been obvious to one of ordinary skill in the art at the time of the invention to adjust therapy based on how frequently a specific type of cardiac rhythm occurs in order to manage the arrhythmia appropriately and allocating only what energy is necessary for each type of therapy.

36. Regarding Claims 16 and 17, Causey discloses that the predetermined criteria includes criteria associated with a change in a type of cardiac rhythm occurring prior to the delivery of the ATP therapy (see col. 9, lines 62-65). The examiner considers that

the ICD is programmed to recognize the change from a normal cardiac rhythm to a tachycardia rhythm and is therefore a predetermined criterion that is necessarily incorporated into the ICD. Causey does not explicitly disclose that the criteria are associated with a change in a type of cardiac rhythm during the delivery of ATP therapy. Haluska discloses transitioning therapy modes based on a change in rhythm during ATP therapy (see col. 7, lines 38-44; col. 9, lines 17-22; and col. 13, lines 58-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to allow Causey's control system to transition between modes during ATP therapy because Haluska teaches the benefit of having additional or backup capabilities for terminating tachycardias in the event of acceleration and reducing the risks involved with more serious cardiac arrhythmias.

Conclusion

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
9/1/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766